



**Templates Part II**  
**Interim Progress Report - Budget Period Three**  
**Workplan - Budget Period Four**  
**Focus Area C: Laboratory Capacity—Biologic Agents**

**Budget Period Three Progress Report**

Using the Interim Progress Report template below, provide a brief status report that describes progress made toward achievement of each of the *critical capacities* and *critical benchmarks* outlined in the continuation guidance issued by CDC in February 2002. Applicants should describe their agency's overall success in achieving each critical capacity. The progress report narratives should not exceed 1 page, single-spaced, for each critical capacity. Applicants are welcome to use bullet-point format in their answers, so long as the information is clearly conveyed in the response.

**CRITICAL CAPACITY:** To develop and implement a jurisdiction-wide program to provide rapid and effective laboratory services in support of the response to bioterrorism, other infectious disease outbreaks, and other public health threats and emergencies.

*Provide an update on progress during Project Year III toward achieving this critical capacity:*

During the 2002-03 Supplemental Bioterrorism Grant period, the Washington Public Health Laboratories (WAPHL) made significant progress toward goals established by HHS and CDC. Overall, improvements were made in the establishment and training of Level A/B laboratories, communication with first responders, and in development of an integrated response plan in Washington State for bioterrorism, other outbreaks of infectious disease, and other public health threats and emergencies. During the past twelve months, using funding provided by HHS and CDC, the WAPHL made the following improvements in its integrated plan for laboratory response to bioterrorism:

1. The WAPHL prepared and followed a timeline for development of a plan to improve working relationships and communication between Level A (clinical) laboratories and Level B and C Laboratory Response Network (LRN) laboratories in order to ensure that Level A laboratories maintain core capability to: perform rule-out testing on critical bioterrorism agents; safely package and handle specimens; and refer to higher level laboratories for further testing. WAPHL hired a Laboratory Program Advisor and a Laboratory Information Management System (LIMS) Coordinator to implement critical program activities. Lines of communication were expanded through development of workgroups with hospitals/laboratories, veterinarians, other state and federal agencies (leading to formal cooperative agreements), and the public health systems of other countries in the region.
2. The WAPHL made significant progress toward development of an integrated response plan will direct Washington State laboratories' response to incidents of bioterrorism. Steps included carefully defined roles and responsibilities, inter- and intra-jurisdictional surge capacity, integration with other department-wide emergency response efforts, protocols for safe transport of specimens by air and ground, and improved/new lab result protocols for local



- public health and law enforcement agencies. Consolidated contracts with local health jurisdiction laboratories have resulted in improved communication as well as progress toward bringing these facilities up to full Level B capability. Training aimed at improving the competency of Level A/B laboratories to “Rule-out or Refer” and to safely ship specimens has continued. In collaboration with Focus Area E, progress has also been made toward establishment of secure electronic linkages for reporting results in real-time.
3. The WAPHL has made limited progress in establishing operational relationships with local members of HazMat teams, first responders, and FBI to provide laboratory support for their response to bioterrorism. Long-term plans call for enhancement of these relationships through establishment of designated points of contact, cross-training and/or joint sponsorship of conferences. Unanticipated delays in hiring key personnel have slowed progress in this area. There has, however, been excellent progress toward training the WAPHL’s new Laboratory Program Advisor and in the enhancement of WAPHL management activities (such as specimen receipt, testing, and reporting of laboratory data).
  4. The WAPHL has made excellent progress toward enhancement of relationships with community laboratory practitioners, university laboratories, and infectious disease physicians during the 2002-03 grant period. Recent collaborations have led to opportunities to work with Clinical Laboratory Advisory Council (CLAC) members and through this avenue improve the region’s capability to deal with the possible reemergence of smallpox. Also, WAPHL managers and staff have, with the assistance of federal funding, been able to participate regularly in infectious disease rounds and conferences and to present findings concerning the assessment of molecular methodologies for agents of bioterrorism.
  5. The WAPHL has been successful in the development of procedures and in training personnel to collect, process, and transport blood and urine samples to CDC for analysis of both chemical and biological agents. Plans for collection, processing and transport of samples have been carefully reviewed and are consistent with CDC-supplied protocols. Current procedures ensure careful coordination will take place between CDC and the WAPHL when specimens are to be forwarded for testing. The WAPHL has also been successful in developing a database for tracking and reporting of referred (including pass-through) specimens to reference laboratories.

**Critical Benchmark #10:** Has your state developed a plan to improve working relationships and communication between Level A (clinical) laboratories and Level B/C Laboratory Response Network labs to ensure Level A core capabilities (perform rule-out testing on critical BT agents, safely package and handle specimens, refer to higher level (B/C) labs for further testing) ?

☒ YES      ☐ NO

**CRITICAL CAPACITY:** As a member of the Laboratory Response Network (LRN), to ensure adequate and secure laboratory facilities, reagents, and equipment to rapidly detect and correctly identify biological agents likely to be used in a bioterrorist incident.



*Provide an update on progress during Project Year III toward achieving this critical capacity:*

1. The WAPHL successfully developed operational plans and protocols that provide safe transportation of samples, improved safety, enhanced triage capabilities, and updated procedures for handling bioterrorism agents during the past year. Equipment has been purchased and installed that has significantly improved the safety of laboratory personnel as well as the security of select agents. Using CDC funding, the WAPHL hired qualified personnel to carry out key bioterrorism-related testing and reporting activities. State and local public health staff were trained in the use of updated LRN protocols as the CDC approved them. This has helped the WAPHL to maintain an adequate number of trained staff to handle public health emergencies. In the 2003-04 Bioterrorism Response Grant period, the WAPHL is requesting additional CDC support in the form of a qualified trainer capable of working directly with local health jurisdictions, first responders, the FBI and other key emergency response personnel to thoroughly train/update them on current laboratory-related protocols and to help create a seamless bioterrorism response and infectious disease surveillance network in Washington State. Recent experience in emergency response coordination efforts has clearly demonstrated the need for such a trainer to strengthen the critical link between first responders and the WAPHL. The WAPHL Safety and Quality Control Coordinator has revised and updated laboratory protocols (i.e., risk assessment, employee competency, test validation, proficiency testing, etc) to ensure the appropriate documentation of laboratory operations.
2. The WAPHL has continued to work to ensure that public health capacity exists for LRN-validated testing by carefully monitoring the LRN website for updated protocols and obtaining the necessary equipment, supplies and reagents to maintain and improve readiness. In the past year, for example, the WAPHL has purchased state of the art equipment such as [REDACTED], in order to maintain readiness and provide test results that are as close to real-time as possible. The purchase of additional state-of-the-art laboratory equipment through CDC funding resources has also allowed the WAPHL to expand its list of available test methods to include additional bioterrorism-related microorganisms, bio-toxins and chemicals. Overall, improvements in preparedness and response to bioterrorism have significantly increased the efficiency of routine diagnosis, surveillance and epidemiologic investigations. The focus on methods development, using amplification techniques with real-time PCR and direct probes, has been successful as a result of mutual collaborations with the University of Washington in Seattle. For example, significant progress has been made in the past year in the development of Fluorescent *in-situ* Hybridization (FISH) technology targeting systemic diseases (tularemia, brucellosis, yersiniosis, reckettsiosis) and diseases of the respiratory tract (pulmonary anthrax, Q-fever, coccidiomycosis, etc.).
3. Through the use of state consolidated contracts with local health jurisdiction laboratories in both eastern and western Washington, the WAPHL has worked to ensure that public health support laboratories have appropriate instrumentation and appropriately trained staff to provide necessary surge capacity for bioterrorism response and other public health emergencies. The Washington State Department of Health (DOH) has also developed plans to further expand the number of laboratories in the state capable of providing Level B LRN



support. In collaboration with the CDC, expanded foodborne disease testing protocols are being established to include botulism, etc., in food and water. Testing algorithms have also been established for use with updated protocols at the WAPHL.

4. The WAPHL was able to conduct/participate in bioterrorism simulation exercises in the past year in preparation for a possible bioterrorism-related event. Overall, the results of simulation exercises have been encouraging and have allowed WAPHL management and staff to identify improvements that will be necessary for a truly seamless emergency response system. Through CDC funding provided for the strengthening of the public health response to bioterrorism, other infectious disease outbreaks, and other public health threats and emergencies, the WAPHL has formulated plans to strengthen what are clearly vital links between first responders, local and state public health, and federal agencies. An assessment was also made of the bioterrorism-related proficiency testing materials available to LRN laboratories in Washington State. Thanks to proactive efforts by the CDC, regular proficiency challenge samples are routinely available for LRN approved test methods. WAPHL is actively involved in this quality assurance program. The WAPHL is also participating in bioterrorism-related proficiency testing available through the College of American Pathologists (CAP) and strongly encourages all certified LRN laboratories in the state to participate as well.

5. The WAPHL has been working diligently to ensure that additional Bio-Safety Level 3 (BSL-3) facilities are available for surge capacity. [REDACTED]

[REDACTED] These facilities are in the process of being evaluated to ensure that they meet standards established for safe practices in the CDC-NIH Biosafety in Microbiological and Biomedical Laboratories (BMBL) manual, 4<sup>th</sup> Edition. Steps are also being taken to evaluate and enhance protocols that will allow existing BSL-2 facilities to follow BSL-3 practices as outlined in the BMBL manual.

6. The WAPHL has been very active in upgrading laboratory security and safety to make it consistent with recommendations established in the BMBL manual (and updates). This has included the use of consultants for improvement of laboratory security as well as specialists in laboratory safety. Bioterrorism grant funding provided through the CDC has been used directly to upgrade the laboratory facility. Additional work has also been accomplished in the retrofitting of the WAPHL facility to withstand local seismic activity. Through funding provided by the Bioterrorism Response Grant, the development of a laboratory information management system (LIMS) is also moving forward through direct WAPHL involvement in an (Association of Public Health Laboratories) APHL sponsored project to identify business process requirements for public health laboratory LIMS. Additional work is planned, in cooperation with the APHL, for implementation of a LIMS at the WAPHL through a collaborative development project.
7. In cooperation with Focus Area E (Health Alert Network/Communications and Information Technology) the WAPHL is involved in the enhancement of electronic communications within the LRN through purchase of high-speed equipment, implementation of the National Electronic Disease Surveillance System (NEDSS), upgrade of the Spokane regional Health



Department (SRHD) Laboratory, and a database of both private and public health laboratories. The WAPHL has upgraded computer hardware in the laboratory in order to ensure reliable high-speed connection. Improvements in electronic communications, coordinated by the CDC, now support proficiency testing programs that allow multicenter validation studies.



## Budget Year Four Workplan

For each Recipient Activity applicants should complete the work plan templates attached below. Applicants are welcome to use bullet-point format in their answers, so long as the information is clearly conveyed in the response. All responses should be brief and concise. **Please note that full use of the CDC templates will meet all of the requirements for submission of a progress report and work plan.** Although no additional information is required, grantees may elect to submit other essential supporting documents via the web portal by uploading them as additional electronic files.

**CRITICAL CAPACITY #8:** To develop and implement a jurisdiction-wide program to provide rapid and effective laboratory services in support of the response to bioterrorism, other infectious disease outbreaks, and other public health threats and emergencies.

### RECIPIENT ACTIVITIES:

1. Develop and maintain the capability of Level A (sentinel) laboratories to (a) perform rule-out testing on critical BT agents, (b) safely package and handle specimens, and (c) refer to LRN Level B/C (reference/confirmatory) laboratories for further testing. **(LINK WITH FOCUS AREAS D AND G AND HRSA PRIORITY AREA #4)**

*Strategies: What overarching approach(es) will be used to undertake this activity?*

1. Increase funding to include an additional Laboratory Program Advisor (LPA) for focus on communication and coordination between WAPHL and sentinel laboratories to ensure the pursuit, organization, management, and accomplishment of program activities
2. Maintain funding for LIMS Coordinator to continue development on interoperable LIMS
3. Maintain lines of communication with Level A Laboratories (ELaborations, Training, etc)
4. Survey analytical (clinical and environmental; chemical and biological; veterinary; public, private and academic) laboratories regarding emergency response (FOCUS AREA D AND HRSA LINK)
5. Continue plan for training of Level A laboratories - Link with plan to collect laboratory-specific emergency response information (Link to Focus area G)
6. Revise and update database of Washington's Level A/B laboratories
7. Coordinate hospital laboratory activities and infrastructure (e.g., staff travel) funded through the HRSA Cooperative Agreement
8. Work with Level A/B labs to meet shipping guidelines for specified Department of Transportation and International Air Transport Association (IATA) shipping regulations (HRSA funding)
9. Assess sentinel laboratories for safe practices
10. Produce training website for on-line registration and distribution of training materials and information regarding LRN response to bioterrorism-related issues. (Link to focus area G)

*Tasks: What key tasks will be conducted in carrying out each identified strategy?*





- 1a Support travel of LPA to local, regional and national meetings/conferences
- 1b Support training and travel in the APHL Incident Command System (see APHL Guidance, p 34).
- 1c Travel for Level A/B planning/training funded through HRSA
- 1d Hire second LPA
- 1e Travel for packaging and shipping training
- 1f Purchase equipment/supplies to support FTE
- 2a Participate in APHL conference calls
- 2b Attend APHL meetings for coordination of LIMS development
- 2c Evaluate collaborative vendor purchase and development options
- 3a [REDACTED] uniform protocols for screening and collecting BT specimens and specimen triage to ensure that only properly screened, appropriate specimens are submitted to the WAPHL for testing.
- 3b Present to LHJs (including surveillance and Epi-response staff, and health officers), HazMat teams and EOC uniform protocols for screening and collection of BT specimens and specimen triage to ensure that only properly screened and appropriate specimens are submitted to the WAPHL for testing.
- 3c Develop a written integrated lab response plan for BT to sentinel labs that includes input from sentinel laboratories, LHJs, Epidemiology and the CDC.
- 3d Distribute a written integrated lab response plan for BT to sentinel labs
- 3e Establish and enhance lines of communication with sentinel laboratories through site visits and regional meetings
- 3f Encourage proficiency testing by sentinel labs
- 4a Develop survey with CDC collaboration
- 4b Administer survey and analyze data
- 4c Use survey results in BT planning
- 5a Review survey of analytical labs and update training plan
- 5b Identify laboratories in need of training
- 5c Schedule training for Level A labs
- 6 Update database to include all analytical laboratories in region
- 7a Notify Level A hospital laboratories of travel funding through HRSA for training
- 7b Provide BT funding to hospital labs for proficiency testing through HRSA
- 7c Notify hospital labs of funding available through HRSA for DOT & IATA-approved shipping containers
- 8a Purchase shipping containers that meet current regulations for non-hospital laboratories
- 8b Distribute shipping containers to non-hospital labs
- 9a Include questions about safe practices in analytical lab survey
- 9b Include training in safe practices in Level A training
- 10a Contract for web design and build
- 10b Implement and maintain web page

*Timeline: What are the critical milestones and completion dates for each task?*

- 1a Ongoing
- 1b 4/2004



1c	11/2003
	2/2004
	5/2004
	8/2004
1d	10/03
1e	11/2003
	2/2004
	5/2004
	8/2004
1f	10/03
2a-b	Ongoing
2c	12/2003
3a	12/03
3b	2/04
	5/04
	8/04
3c	10/03
3d	2/04
	5/04
	8/04
3e-f	Ongoing
4a	12/03
4b	1/04
4c	6/04
5a-b	2/4
5c	2/04
6	Ongoing
7a	12/03
7b	10/03
7c	10/03
8a-b	Ongoing
9a	12/03
9b	2/04
	5/04
	8/04
10a	7/04
10b	Ongoing

*Responsible Parties: Identify the person(s) and/or entity assigned to complete each task.*

1a	LPA
1b	BT Coordinator
1c	LPA
1d	Operations Manager
1e	LPA
1f	Operations Manager





2a-c BT Coordinator  
3a Micro OD  
3b LPA  
3c Div ERP  
3d-f LPA  
4a-b Training Manager  
4c LPA  
5a-c LPA  
6 Training Manager  
7a LPA  
7b LQA  
7c LQA  
8a-b Operations Manager  
9a Training Manager  
9b LPA  
10a Operations Manager  
10b LIMS Coordinator

*Evaluation Metric: How will the agency determine progress toward successful completion of the overall recipient activity?*

1a-b Meeting attendance  
1c Training documents  
1d Employment acceptance  
1e Training documents  
1f Purchase order  
2a-b Notes  
2c Meeting notes & documents  
3a Published protocols  
3b Class attendance  
3c Published Plan  
3d Class attendance  
3e Meeting attendance  
3f Training plan  
4a-b Survey  
4c Survey data  
5a Survey data  
5b Training courses  
5c Class schedule  
6 Database  
7a Meeting attendance  
7b-c *ELaborations* Article  
  
8a Purchase orders  
8b Incoming samples  
9a Survey



9b Training Materials  
10a-b Website

11. **CRITICAL BENCHMARK #12:** Complete and implement an integrated response plan that directs how public health, hospital-based, food testing, veterinary, and environmental testing laboratories will respond to a bioterrorism incident, to include: (a) roles and responsibilities; (b) inter- and intrajurisdictional surge capacity; (c) how the plan integrates with other department-wide emergency response efforts; (d) protocols for safe transport of specimens by air and ground; and (e) how lab results will be reported and shared with local public health and law enforcement agencies, ideally through electronic means. **(LINK WITH FOCUS AREAS A, B, D, E AND F, and CROSS CUTTING ACTIVITY LABORATORY CONNECTIVITY, Attachment X)**

*Strategies: What overarching approach(es) will be used to undertake this activity?*

1. Finalize/update BT response protocols with Epidemiology and integrate with other department-wide emergency response efforts (include public health, hospital-based, food testing, veterinary, and environmental testing)
2. Continue development of Memoranda of Understanding (MOU) with reference laboratories (Surge Capacity) to include food testing, veterinary, and environmental testing
3. Update training manual for Level A laboratories' roles and responsibilities and distribute (Link to focus area G)
4. Update protocols used for triage and specimen collection.
5. Update and distribute protocols for safe transport of specimens.
6. Define and publish turn-around times (TAT) in training manual and *Elaborations* (Link to focus area G)
7. Update reporting protocols to specify how lab results will be reported and shared with Epidemiology, local public health and law enforcement agencies
8. Purchase equipment to communicate with stakeholders (APHL guide)
9. Collaborate with the Washington Animal Diseases Diagnostic Laboratory (WADDL) to prepare for and respond to acts of bioterrorism or to other public health emergencies. This includes [REDACTED] and supporting laboratory capacity for sentinel animal disease surveillance; providing veterinary diagnostic laboratory support in meeting the counter-terrorism mission of the state public health department; providing WADDL with support to enhance capability to diagnose overlap agents in animals, food, and low risk environmental samples; and supporting laboratory capacity for diagnosis of an intentionally introduced agent in animals (Link with Focus area B).
10. The WAPHL will, in consultation with the CDC and other federal/state agencies, compile a region-wide inventory of all analytical laboratories through a comprehensive survey. In this survey, the WAPHL will assess the current capabilities and capacities of laboratories in the



region as well as their current capabilities and needs related to “peri-“ and “post-“ event involvement in emergency response activities. This survey will be administered to public and private food testing laboratories, veterinary laboratories, environmental testing laboratories, hospital/clinical laboratories (including academic health centers), regional/local public health laboratories, public health laboratories of countries and states that share our borders, etc. These are laboratories that could potentially play an important role in helping public health officials respond to biological and/or chemical acts of terrorism or other public health emergencies. A summary of survey data will be compiled and a database of regional laboratory capabilities will be developed. (LINK BETWEEN FOCUS AREAS A, B, C, D, E, F, G AND HRSA PRIORITY AREA #4, Cross-cutting Benchmark #3)

11. The WAPHL will, as part of the comprehensive survey mentioned above, determine what formal and informal cooperative agreements currently exist in and among laboratories (both public and private) in the region. (LINK BETWEEN FOCUS AREAS C AND D)
12. The WAPHL will consider the results of this needs assessment survey when planning and implementing enhancements to the public health infrastructure of the state. (LINK BETWEEN FOCUS AREAS C AND D)
13. The WAPHL will consider the results of this needs assessment survey when implementing new or improved cooperative agreements between laboratories in the region. (LINK BETWEEN FOCUS AREAS C AND D)
14. The WAPHL will integrate new advanced rapid identification methods approved by the LRN into the current laboratory-testing algorithm for human, environmental, animal or food specimens. (LINKS BETWEEN FOCUS AREAS B, C AND D)
15. The WAPHL, in collaboration with cooperating partners (including hospital laboratories), will conduct a simulation exercise involving at least one biological and chemical threat agent that specifically tests laboratory readiness and capability to perform specimen threat assessment, intake prioritization, testing, confirmation, and results reporting using the LRN website. (LINK BETWEEN FOCUS AREAS A, C, D AND G)
16. The WAPHL will ensure that laboratory registration, operations, safety, and security are consistent, at a minimum, with the requirements set forth in Select Agent Regulation (42 CFR 73) and the Patriot Act of 2001. (LINK BETWEEN FOCUS AREAS C AND D)
17. The WAPHL will enhance electronic communications and Washington Electronic Disease Surveillance System (WEDSS) reporting to enable integration with LRN plans (Including the use of LOINC codes for the reporting of test results). (LINK BETWEEN FOCUS AREAS C, D AND E, and HRSA Priority Area #4, Cross-cutting Benchmark #4)
18. The WAPHL will work on pre-event smallpox planning and coordination to identify laboratories that have the capacity for LRN-validated testing and reporting of Variola major, Vaccinia and Varicella through human and environmental samples. This collaboration also includes review of established smallpox emergency procedures and specimen collection supplies. (LINK BETWEEN FOCUS AREAS B AND C)

*Tasks: What key tasks will be conducted in carrying out each identified strategy?*

- 1a Attend 50 state Focus Area C/D Conference in late 2003 (request travel)
- 1b Evaluate the National Laboratory Database of key partners developed by DLS/PHPPO
- 1c Review and update PHL protocols in cooperation with CDC and EHSPHL to ensure



- integration
- 2a Update existing MOUs as needed
- 2b Complete implementation of MOUs
- 3a Review analytical lab survey data
- 3b Update training manual using survey summary data
- 4 Update protocols in collaboration with EHSPHL (LINK TO FOCUS B)
- 5a Update safe transport protocols
- 5b Distribute protocols to Level A/B labs
- 6a Update and publish Turn-Around Times (TAT)
- 6b Schedule publication of TATs in *Elaborations* and website
- 7a Update reporting protocols (including back-up reporting systems) to conform with CDC recommendations
- 7b Publish reporting protocols
- 7c Include reporting protocols in training manual
- 8a Evaluate equipment needs for required communication
- 8b Purchase communication equipment
- 9a In conjunction with Focus area B activities, assess capacity and develop strategies for [REDACTED] sentinel zoonotic disease surveillance in animals to enhance early detection of public health threats and bioterrorism events.
- 9b WADDL will, in collaboration with DOH, [REDACTED] zoonotic agents of concern for sentinel animal disease surveillance.
- 9c WADDL will [REDACTED] enhanced laboratory capacity for diagnosis of the prioritized agents in cooperation with WAPHL.
- 9d WADDL will hire and train a microbiologist to perform assays as requested by DOH
- 9e WADDL will provide capacity to perform necropsy and histopathology on animals that die of unusual disease.
- 10a Consult with the CDC and other federal/state agencies on development of inventory of analytical laboratories
- 10b Develop survey
- 10c Administer survey
- 10d Analyze/summarize survey
- 11a Summarize existing cooperative agreements
- 11b Use summary in development of WAPHL plans for LRN
- 12 Use survey results in development of plans
- 13 Use survey summary in planning for cooperative agreements
- 14a Identify new approved methods on the LRN website
- 14b Implement methods and integrate into current laboratory testing algorithm
- 15a Plan cooperative exercise with partners
- 15b Participate in simulation exercise
- 15c Summarize cooperative exercise with partners
- 15d Implement suggested changes
- 16a Review Select Agent Regulation (42 CFR 73) and the Patriot Act of 2001
- 16b Update laboratory registration, operations, safety, and security as required
- 17 Ensure WAPHL LIMS development integrates with LRN and APHL plans



- |     |  |
|-----|--|
| 18a | Ensure survey of analytical laboratories identifies capacities for smallpox testing and referral     |
| 18b | Review and update smallpox emergency procedures and potential needs for specimen collection supplies |

*Timeline: What are the critical milestones and completion dates for each task?*

- |       |           |
|-------|-----------|
| 1a    | 10/03     |
| 1b    | 12/03     |
| 1c    | Ongoing   |
| 2a    | 12/03     |
| 2b    | 8/04      |
| 3a-b  | 3/03      |
| 4     | 10/03     |
| 5a-b  | 10/03     |
| 6a    | Biannual  |
| 6b    | As needed |
| 7a-b  | 12/03     |
| 7c    | 1/04      |
| 8a-b  | 12/03     |
| 9a    | 2/04      |
| 9b    | 12/03     |
| 9c    | 2/ 04     |
| 9d    | 2/04      |
| 9e    | 12/03     |
| 10a-b | 12/03     |
| 10c   | 1/04      |
| 10d   | 6/04      |
| 11a   | 12/03     |
| 11b   | 4/04      |
| 12    | 6/04      |
| 13    | 6/04      |
| 14a-b | Ongoing   |
| 15a   | Ongoing   |
| 15b-d | 8/04      |
| 16a   | 9/03      |
| 16b   | 12/03     |
| 17    | Ongoing   |
| 18a   | 12/03     |
| 18b   | Ongoing   |

*Responsible Parties: Identify the person(s) and/or entity assigned to complete each task.*

- |    |   |
|----|---|
| 1a | Director DOH Office of Environmental Sciences and Director Office of Public Health Microbiology (Micro) |
| 1b | LIMS Coordinator  |
| 1c | Div ERP   |



2a-b PHL Dir  
3a-b Training Manager  
4 Micro Office Director  
5a Micro Office Director  
5b LPA  
6a-b Micro Office Director  
7a-b Micro Office Director  
7c LPA  
8a-b LIMS Coordinator  
9a-e WADDL  
10a-d Training Manager  
11a-b Micro Office Director  
12 Training Manager  
13 Micro Office Director  
14a-b Micro Office Director  
15a Div ERP  
15b-c PHL Director  
15d Ops Manager  
16a-b Div ERP  
17 LIMS Coordinator  
18a Training Manager  
18b Ongoing

*Evaluation Metric: How will the agency determine progress toward successful completion of the overall recipient activity?*

1a Travel documentation  
1b Database evaluation  
1c Updated protocols  
2a-b Finalized MOUs  
3a-b Updated manual  
3b Updated manual  
4 Updated protocols  
5a-b Updated protocols  
6a Updated TAT  
6b Publication  
7a-c Updated protocol  
8a Equipment list  
8b Purchase orders  
9a Assessment done  
9b Priorities listed  
9c Tests identified  
9d FTE filled  
9e Necropsy reports  
10a Inventory



- 10b-c Survey
- 10d Survey summary
- 11a Summary
- 11b WAPHL Plans
- 12 WAPHL plans
- 13 Survey summary
- 14a Methods
- 14b Testing algorithm
- 15a-b Plan
- 15c Exercise summary
- 15d List of changes
- 16a Regulations
- 16b Plan for upgrade
- 17 LIMS Development plan
- 18a Survey
- 18b Review document

12. In accord with Critical Benchmark #12, address the identified needs for testing food specimens for critical BT pathogens. This may be done by contracting for services with laboratories that possess the requisite capabilities, by sponsoring such capability development within collaborating organizations (such as food regulatory laboratories), and/or by developing the requisite capabilities directly within public health department laboratories. Technical assistance with respect to selection of analytic methods is available through FDA, in consultation with CDC (see Appendix 1 for FDA contact information).

*Strategies: What overarching approach(es) will be used to undertake this activity?*

- 1. Continue collaborations with FDA Bothell for surge capacity through MOU and cross training program (Link to focus area G)
- 2. Compile/Update food testing protocols for BT specimens
- 3. Continue development of analytical methods used for BT testing and coordinate with analytic methods used by FDA (in consultation with CDC)
- 4. Continue collaborations with WA Dept of Ag in Olympia and Yakima through MOU
- 5. Implement BotTox ELISA assay - equipment and reagents from CDC

*Tasks: What key tasks will be conducted in carrying out each identified strategy?*





- |    |   |
|----|---|
| 1a | Finalize FDA MOU  |
| 1b | Continue cross training with FDA staff                          |
| 1c | Share necessary protocols with FDA                              |
| 2a | Evaluate need for food testing protocols                        |
| 2b | Update food testing protocols to meet CDC and FDA requirements  |
| 2c | Distribute food testing protocols as needed                     |
| 3a | Update food testing protocols to meet CDC and FDA requirements  |
| 3b | Purchase equipment for implementation of food testing protocols |
| 4  | Establish MOU with WA Dept of Agriculture laboratories          |
| 5  | Perform BotTox ELISA cross-training at PHL                      |

*Timeline: What are the critical milestones and completion dates for each task?*

- |      |         |
|------|---------|
| 1a   | 12/03   |
| 1b-c | Ongoing |
| 2a   | 10/03   |
| 2b   | 12/03   |
| 2c   | 1/04    |
| 3a   | 12/03   |
| 3b   | 1/04    |
| 4    | 12/03   |
| 5    | 9/03    |

*Responsible Parties: Identify the person(s) and/or entity assigned to complete each task.*

- |       |          |
|-------|----------|
| 1a    | PHL Dir  |
| 1b-1c | Micro OD |
| 2a-3b | Env OD   |
| 4     | PHL Dir  |
| 5     | Micro OD |

*Evaluation Metric: How will the agency determine progress toward successful completion of the overall recipient activity?*

- |      |                          |
|------|--------------------------|
| 1a   | Completed MOU            |
| 1b   | Completed cross-training |
| 1c   | Completed protocols      |
| 2a   | List of protocols        |
| 2b-c | Completed protocols      |
| 3a   | Completed protocols      |
| 3b   | Purchase orders          |
| 4    | Completed MOU            |
| 5    | Training attendance      |

13. Establish and maintain operational relationships with local members of HazMat teams, first responders, local law enforcement and FBI to provide laboratory support for their



response to bioterrorism, including environmental testing for exposure assessment and chain-of-custody procedures. Examples of enhanced these relationships include designated points of contact, cross-training in each discipline, and/or joint sponsorship of conferences. **(LINK WITH FOCUS AREA D)**

*Strategies: What overarching approach(es) will be used to undertake this activity?*

1. Update and finalize database of first responder points of contact.
2. Expand the plan for training and collaboration with first responders. Enhance relationships by conducting regional meetings/conferences with HazMat teams, local law enforcement agencies and other first responders. Ensure first responders as well as regional and local public health are involved in training and collaboration (Link to focus area G)
3. Continue planning and implementation of PHL Central Receiving.
4. Plan and hold meeting with key partners to discuss plans during periods of increased activity.

*Tasks: What key tasks will be conducted in carrying out each identified strategy?*

- 1 Update/maintain database to include all first responder groups in WA
- 2a Plan meetings with first responder groups
- 2b Identify training contacts of first responders and implement a train-the-trainer program.
- 3a Identify next steps for planning of Central Receiving Facility
- 3b Contract AE firm for design
- 3c Identify capital improvement and equipment needs
- 3d Determine staffing needs for Central Receiving Facility
- 4a Identify partners necessary for effective planning
- 4b Schedule meeting with key partners
- 4c Implement findings/updated plans

*Timeline: What are the critical milestones and completion dates for each task?*

- 1 8/03
- 2a 10/03
- 2b 1/04
- 3a 9/03
- 3b 11/03
- 3c 1/04
- 3d 5/04
- 4a 10/03
- 4b 1/04
- 4c 8/04

*Responsible Parties: Identify the person(s) and/or entity assigned to complete each task.*

- 1 Training Manager
- 2a-b LPA
- 3a-d Operations Manager
- 4a-c Div ERP



*Evaluation Metric: How will the agency determine progress toward successful completion of the overall recipient activity?*

- 1 Database
- 2a Meeting agendas
- 2b Training schedule
- 3a Plans
- 3b Contract
- 3c Equipment List
- 3d Needs List
- 4a List of partners
- 4b Agenda
- 4c Plans

14. Enhance relationships with hospital-based laboratory practitioners, university laboratories, and infectious disease physicians through participation in infectious disease rounds and conferences. **(LINK WITH FOCUS AREA D)**

*Strategies: What overarching approach(es) will be used to undertake this activity?*

- 1. Continue development of secure web-based BT information for Level A/B LRN laboratories in Washington
- 2. Continue outreach to professional organizations/agencies using innovative electronic communication systems.
- 3. Develop/expand general bioterrorism guidelines for response to BT events
- 4. Continue to publish and distribute articles in periodicals such as the *Elaborations* newsletter in order to provide pertinent information to LRN laboratories
- 5. Update current list of professional organizations and laboratory groups for use in identifying conferences (local and national).
- 6. Continue methods development and present findings at national/ international conferences
- 7. Attend meetings and seminars such as “Show and Tell” and “grand rounds” at area laboratories and hospitals.

*Tasks: What key tasks will be conducted in carrying out each identified strategy?*

- 1a Contract for web design and build (LINK WITH FOCUS AREA E)
- 1b Implement and maintain web page (LINK WITH FOCUS AREA E)
- 2a Attend BT-related conferences
- 2b Plan meetings to discuss BT-related issues with professional organizations
- 3a Review existing guidelines
- 3b Develop/expand guidelines as needed
- 4a Include BT-related subjects in *Elaborations* publications
- 4b Provide funding for publication of *ELaborations*
- 5a Formalize current list of organizations/groups and update
- 5b Join appropriate organizations and attend meetings
- 6a Schedule attendance at conferences
- 6b Prepare and present current information on methods development



- 7a Obtain schedules of hospital seminars
- 7b Schedule attendance at seminars

*Timeline: What are the critical milestones and completion dates for each task?*

- 1a-b Ongoing
- 2a-b Ongoing
- 3a 10/03
- 3b 11/03
- 4a Bimonthly
- 4b 9/03
- 5a 12/03
- 5b 1/04
- 6a-b Ongoing
- 7a-b 9/03

*Responsible Parties: Identify the person(s) and/or entity assigned to complete each task.*

- 1a-b LIMS Coordinator
- 2a-b PHL Dir
- 3a-b Micro OD
- 4a LPA
- 4b LQA
- 5a QA/QC Coordinator
- 5b PHL Dir
- 6a PHL Dir
- 6b Micro OD
- 7a-b PHL Dir

*Evaluation Metric: How will the agency determine progress toward successful completion of the overall recipient activity?*

- 1a Design
- 1b Web page
- 2a Conference List
- 2b Agendas
- 3a List of guidelines
- 3b Updated Guidelines
- 4a Articles
- 4b Publications
- 5a List
- 5b Membership
- 6a List of Conferences
- 6b Presentations
- 7a Schedules
- 7b Schedules



15. (Smallpox) Appoint a liaison from the state or local LRN-member laboratory to participate in meetings and conference calls with smallpox steering committee, stakeholders, and any other activities relevant to LRN operations and smallpox activities.

*Strategies: What overarching approach(es) will be used to undertake this activity?*

1. Appoint liaison from the state or local LRN-member laboratory to participate in meetings and conference calls
2. Expand collaborations with State Emergency Response Coordinators (SERCs) and Regional Emergency Response Coordinators (RERCs) for strengthening of WA Smallpox response plans. (Link to focus area G)

*Tasks: What key tasks will be conducted in carrying out each identified strategy?*

- 1a Identify candidates for liaison
- 1b Appoint/request candidate's participation
- 2a Contact SERCs and RERCs and schedule meetings to discuss collaborations
- 2b Implement plans resulting from collaborative meetings

*Timeline: What are the critical milestones and completion dates for each task?*

- 1a-b 9/03
- 2a-b 10/03

*Responsible Parties: Identify the person(s) and/or entity assigned to complete each task.*

- 1a-b PHL Dir
- 2a-b PHL Dir

*Evaluation Metric: How will the agency determine progress toward successful completion of the overall recipient activity?*

- 1a List of candidates
- 1b Appointment letter
- 2a Meeting schedules
- 2b Plans

**CRITICAL CAPACITY #9:** As a member of the Laboratory Response Network (LRN), to ensure adequate and secure laboratory facilities, reagents, and equipment to rapidly detect and correctly identify biological agents likely to be used in a bioterrorist incident.

RECIPIENT ACTIVITIES:

1. Continue to develop or enhance operational plans and protocols that include: (a) specimen/samples transport and handling; (b) worker safety; (c) appropriate Biosafety Level (BSL) working conditions for each threat agent; (d) staffing and training of personnel; (e) quality control and assurance; (f) adherence to laboratory methods and



protocols; (g) proficiency testing to include routine practicing of LRN validated assays as well as participation in the LRN's proficiency testing program electronically through the LRN website; (h) threat assessment in collaboration with local law enforcement and FBI to include screening for radiological, explosive and chemical risk of specimens; (i) intake and testing prioritization; (j) secure storage of critical agents; and (k) appropriate levels of supplies and equipment needed to respond to bioterrorism events with a strong emphasis on surge capacities needed to effectively respond to a bioterrorism incident.  
**(LINK WITH FOCUS AREA D)**

*Strategies: What overarching approach(es) will be used to undertake this activity?*

1. Enhance established protocols for specimen transport and handling using current guidelines (i.e., DOT and IATA).
2. Expand risk assessment operations to include all BT-related protocols used by the PHL.
3. Review and update appropriate BSL protocols to ensure safe working conditions for each threat agent.
4. Expand staffing and training to ensure adequate levels of routine and emergency testing and safety (Link to focus area G)
5. Continue to develop plans and protocols that include CDC recommended QA/QC for BT
6. Ensure adherence to LRN developed protocols
7. Ensure proficiency testing, including CDC validation studies, PHL competency reviews and CAP BT proficiencies are up to date.
8. Ensure threat assessments for radiological, explosive and chemical risks are current for biological specimens submitted for analysis
9. Review and update specimen triage with Epidemiology
10. Continue plans for secure storage of critical agents
11. Develop a written protocol to ensure appropriate levels of supplies and equipment for BT events (consider need for surge capacity)
12. Purchase equipment and supplies to assure personnel safety, including biosafety cabinets, other biocontainment measures, signage, lockable freezers-refrigerators and incubators, personal protective equipment (PPE) including, PAPRS, N-95 masks, etc
13. Hire additional qualified personnel necessary to use sophisticated instrumentation and other staff necessary to carry out the key BT, related activities (e.g., state lab training coordinator, information technology staff, etc.) of the state public health laboratory.
14. Purchase equipment and supplies needed to respond to infectious disease outbreaks or bioterrorism events.
15. Schedule staff to travel to appropriate bioterrorism courses in laboratory confirmatory (reference) methods and related programs sponsored or co-sponsored by CDC, the NLTN, FDA and/or FSIS (Link to focus area G)
16. Schedule travel and registration fees for staff to attend important conferences, such as the International Conference on Emerging Infectious Diseases, and the annual meeting of the American Society for Microbiology. (Link to focus area G)

*Tasks: What key tasks will be conducted in carrying out each identified strategy?*

- 1a Review updated and current guidelines (i.e., DOT and IATA).



- 1b Update and obtain signatures on updated protocols
- 1c The PHL Integrated Standards and Security Management (ISSM) Committee will review current protocols and recommend enhancement/change based on DOT and IATA guidelines.
- 1d If the ISSM Committee identifies changes in current protocols, such changes will be reviewed by PHL management for cost effectiveness and impact.
- 1e If changes are authorized, training will be developed and implemented on new/revised protocols
- 2a Identify protocols needing assessment
- 2b Perform necessary assessments
- 2c BT protocols will undergo a risk assessment and evaluation prior to implementation
- 2d The Safety Officer, in conjunction with the RO, will develop and implement risk assessments specific to the BT protocols.
- 2e The PHL ISSM Committee will review BT protocols, risk assessments, etc and give approval if acceptable prior to implementation
- 3a Review BSL protocols
- 3b Update protocols and obtain signatures
- 3c The PHL ISSM Committee will recommend changes to current BT BSL protocols and recommend changes based on BMBL guidelines
- 3d If the ISSM Committee identifies changes in current protocols, review by PHL management for cost effectiveness and impact.
- 3e If changes are authorized, training will be developed and implemented on new/revised protocols
- 4a Identify staffing needs through an evaluation of test volumes, expansion plans, risk assessments, etc.
- 4b Hire and/or train additional staff
- 4c Purchase equipment/supplies to support FTE
- 5 Review PHL protocols for BT to ensure CDC recommended QA/QC is followed
- 6 Review and update competency of BT staff
- 7 Review proficiency results to ensure results are up to date
- 8a Collaborate with local law enforcement and FBI to identify protocol for threat assessment
- 8b Develop training strategy
- 8c Train law enforcement and FBI in updated protocols
- 9a Review current triage protocol with Epi
- 9b Update protocol to meet current needs
- 10a Develop and adopt inventory procedures
- 10b Implement consultant recommendations for physical security
- 11a. Maintain inventory of shipping supplies sufficient to meet surge capacity needs
- 11b. Maintain inventory of testing supplies sufficient to meet surge capacity needs
- 11c Identify equipment used for BT requiring maintenance contracts
- 12a Identify PPE and other equipment recommended for personal safety
- 12b Purchase necessary equipment
- 13a Continue funding for Laboratory Program Advisor (LPA)
- 13b Funding for second LPA





- 13c Open register, interview and select qualified Microbiologist III
- 14a. In collaboration with CDC, identify and purchase equipment/supplies required for (a) response to infectious disease outbreaks or bioterrorism events and (b) monitoring of laboratory equipment
- 15a. Identify courses and schedule attendance of bioterrorism response staff to maintain required proficiency
- 16a Identify conferences and schedule attendance of bioterrorism response staff
- 16b Prepare talks on methods development related to bioterrorism response for presentation at conferences

*Timeline: What are the critical milestones and completion dates for each task?*

- 1a-e Ongoing
- 2a-e Ongoing
- 3a-e Ongoing
- 4a Done
- 4b 10/03
- 4c 10/03
- 5a. 12/03
- 6a. Ongoing
- 7a. 9/03
- 8a-b 1/04
- 9a-b 9/03
- 10a 10/03
- 10b 12/03
- 11a-b Done
- 11c 10/03
- 12a 9/03
- 12b 1/04
- 13a-b 10/03
- 13c 9/03
- 14a. 10/03
- 15a. 9/03
- 16a 12/03
- 16b Ongoing

*Responsible Parties: Identify the person(s) and/or entity assigned to complete each task.*

- 1a-b Micro OD
- 1c Div ERP
- 1d Div ERP
- 1e Safety Officer
- 2a-e Div ERP
- 3a-d Div ERP
- 3e Safety Officer
- 4a PHL Dir
- 4b Micro OD



- 4c Micro OD
- 5a. QA/QC Coordinator
- 6a. Micro OD
- 7a. Micro OD
- 8a-c LPA
- 9a-b Micro OD
- 10a Div ERP
- 10b Operations Manager
- 11a Operations Manager
- 11b Micro OD
- 11c Operations Manager
- 12a-b Safety Officer
- 13a-b Operations Manager
- 13c Micro OD
- 14 Micro OD
- 15 Micro OD
- 16a Micro OD
- 16b PHL Dir

*Evaluation Metric: How will the agency determine progress toward successful completion of the overall recipient activity?*

- 1a Updated guidelines
- 1b Updated protocols
- 1c List of protocols
- 1d Updated protocols
- 1e Training plans
- 2a List of protocols
- 2b-d Assessment documentation
- 2e Revised protocols
- 3a List of protocols
- 3b Revised protocols
- 3c Changes
- 3d Reviewed protocols
- 3e Training plan
- 4a Needs list
- 4b Employment offer
- 4c Purchase orders
- 5a Updated protocol
- 6a Competency documentation
- 7a Review documentation
- 8a List of collaborators
- 8b Training plan
- 8c Training schedule
- 9a Suggested changes



- 9b Updated protocol
- 10a Procedures
- 10b Consultant contract
- 11a-b Inventory
- 11c List of equipment
- 12a Equipment list
- 12b Purchase order
- 13a-c Job offer
- 14 Purchase orders
- 15 Schedule
- 16a Schedule
- 16b Prepared talks

2. **CRITICAL BENCHMARK #13:** Ensure capacity exists for LRN validated testing for all Category A agents and other Level B/ C protocols as they are approved.

*Strategies: What overarching approach(es) will be used to undertake this activity?*

- 1. Review PHL capacity for testing of all Category A BT agents.
- 2. Finalize/update MOUs with regional LRN Level B & C laboratories to ensure adequate capacity
- 3. Regularly update/validate LRN protocols from the LRN website.
- 4. Fill and train Microbiologist III position to perform LRN validated procedures. Include travel funds for laboratory personnel to attend CDC sponsored Level C training.
- 5. Ensure PHL staff obtain appropriate vaccinations
- 6. [REDACTED]

*Tasks: What key tasks will be conducted in carrying out each identified strategy?*

- 1 Review/analyze current PHL capacity for testing Category A agents
- 2a Prepare drafts of MOUs
- 2b Share drafts with partners
- 2c Obtain signatures on final draft 3a Monitor LRN website at least weekly
- 3 Perform validations and run necessary QA/QC
- 4a Open Micro register and select names for interview. Offer position
- 4b Train microbiologist to perform LRN validated procedures
- 5a Perform needs assessment for appropriate vaccinations
- 5b Obtain necessary vaccinations for staff
- 6a [REDACTED]

*Timeline: What are the critical milestones and completion dates for each task?*

- 1 9/03
- 2a 11/03
- 2b 12/03
- 2c 2/04
- 3 Ongoing



4a 9/03  
4b 10/03  
5a-b Ongoing  
6 9/03

*Responsible Parties: Identify the person(s) and/or entity assigned to complete each task.*

1 Micro OD  
2a PHL Dir  
2b-c PHL Dir  
3 Micro OD  
4a-b Micro OD  
5a-b Safety Officer  
6 Micro OD

*Evaluation Metric: How will the agency determine progress toward successful completion of the overall recipient activity?*

1 Testing summary  
2a-b Drafts  
2c Final MOUs  
3 Validated protocols  
4a Job offer  
4b Training schedule  
5a Vaccination assessment  
5b Documentation  
6 Documentation

3. Ensure at least one public health laboratory in your jurisdiction has the appropriate instrumentation and appropriately trained staff to perform CDC-developed real-time polymerase chain reaction (PCR) and time-resolved fluorescence (TRF) rapid assays. Integrate new advanced rapid identification methods approved by the LRN into the current laboratory-testing algorithm for human, environmental, animal or food specimens. Contact CDC technical support staff for further information on approved equipment as necessary. **(LINK WITH FOCUS AREA B)**

*Strategies: What overarching approach(es) will be used to undertake this activity?*

1. Identify and integrate advanced rapid identification methods into PHL testing algorithm
2. Consult with CDC on necessary upgrades on new equipment
3. Inventory equipment available for BT testing and purchase necessary approved equipment (include redundant equipment for backup – APHL guidance, p41)
4. Purchase maintenance contracts for BT equipment
5. Request travel and fees for NLTN sponsored events (APHL guidance, p41)

*Tasks: What key tasks will be conducted in carrying out each identified strategy?*

- 1a Closely monitor LRN website for new protocols
- 1b Update testing algorithms following test validation
- 2a Monitor LRN website for recommended equipment upgrades



- 2b Establish plans for integration of new equipment
- 3a Update inventory of approved BT equipment
- 3b Plan for acquisition of necessary/redundant equipment
- 4a Inventory equipment with maintenance contracts and decide on cost benefits of contracts
- 4b Purchase maintenance contracts
- 5 Plan travel for specific events of interest

*Timeline: What are the critical milestones and completion dates for each task?*

- 1a-b Ongoing
- 2a-b Ongoing
- 3a 10/03
- 3b 11/03
- 4a Done
- 4b 9/03
- 5 Ongoing

*Responsible Parties: Identify the person(s) and/or entity assigned to complete each task.*

- 1a-b Micro OD
- 2a-b Micro OD
- 3a-b Micro OD
- 4a-b Micro OD
- 5 Training Manager

*Evaluation Metric: How will the agency determine progress toward successful completion of the overall recipient activity?*

- 1a Schedule
- 1b Testing algorithm
- 2a Schedule
- 2b Plans
- 3a Inventory
- 3b Plan and purchase orders
- 4a Inventory
- 4b Contracts
- 5 Travel schedule

4. **CRITICAL BENCHMARK #14:** Conduct at least one simulation exercise per year, involving at least one threat agent in Category A, that specifically tests laboratory readiness and capability to perform from specimen threat assessment, intake prioritization, testing, confirmation, and results reporting using the LRN website. **(MAY LINK WITH ALL FOCUS AREAS)**

*Strategies: What overarching approach(es) will be used to undertake this activity?*

- 1. Finalize plans for and participate in the upcoming full scale BT exercise involving state, local, regional, hospital and tribal entities (planned for Summer of 2004) (Link with focus area G)



2. Participate in BT exercises with other local/state/federal agencies (Link with focus area G)
3. Assess rule out capabilities of Level A laboratories with challenge sets simulating category A agents

*Tasks: What key tasks will be conducted in carrying out each identified strategy?*

- 1a Define PHL role in exercise
- 1b Attend planning meetings
- 2a Evaluate exercise outcomes and summarize strengths/weaknesses
- 2b Define and implement necessary changes
- 3a Continue participation in CAP BT proficiency program
- 3b Continue participation in CDC validation and proficiency programs

*Timeline: What are the critical milestones and completion dates for each task?*

- 1a 2/04
- 1b Ongoing
- 2a-b 8/04
- 3a-b Ongoing

*Responsible Parties: Identify the person(s) and/or entity assigned to complete each task.*

- 1a-b Div ERP
- 2a-b Div ERP
- 3a QA/QC Coordinator
- 3b QA/QC Coordinator

*Evaluation Metric: How will the agency determine progress toward successful completion of the overall recipient activity?*

- 1a Defined roles
- 1b Agendas
- 2a Evaluation
- 2b Revised procedures
- 3a Proficiency schedule
- 3b Proficiency results

5. Ensure the availability of at least one operational Biosafety Level 3 (BSL-3) facility in your jurisdiction. If not immediately possible, BSL-3 practices, as outlined in the CDC-NIH publication “Biosafety in Microbiological and Biomedical Laboratories, 4<sup>th</sup> Edition” (BMBL), should be used (see [www.cdc.gov/od/ohs](http://www.cdc.gov/od/ohs)) or formal arrangements (i.e., MOU) should be established with a neighboring jurisdiction to provide this capacity.

*Strategies: What overarching approach(es) will be used to undertake this activity?*

1. Update MOUs with [REDACTED] and neighboring states, for partnership in BSL-3 back-up capacity (immediate surge capacity)

*Tasks: What key tasks will be conducted in carrying out each identified strategy?*



- 1a Prepare drafts of MOUs
- 1b Share drafts with partners
- 1c Obtain signatures on final draft

*Timeline: What are the critical milestones and completion dates for each task?*

- 1a 11/03
- 1b 12/03
- 1c 2/04

*Responsible Parties: Identify the person(s) and/or entity assigned to complete each task.*

- 1a-c PHL Director

*Evaluation Metric: How will the agency determine progress toward successful completion of the overall recipient activity?*

- 1a Draft
- 1b E-mail
- 1c Final Draft

6. Ensure that laboratory registration, operations, safety, and security are consistent, at a minimum with the requirements set forth in Select Agent Regulation (42 CFR 73) “Possession, Use and Transfer of Select Agents and Toxins; Interim Final Rule” and any subsequent updates as detailed in [www.cdc.gov/od/sap](http://www.cdc.gov/od/sap) and [www.aphis.usda.gov/vs/ncie/bta.html](http://www.aphis.usda.gov/vs/ncie/bta.html). Pursuant to 18 USC section 175b, as added by section 817 of the USA PATRIOT Act of 2001, P.L. 107-56, aliens (other than aliens lawfully admitted to the United States for permanent residence) are prohibited from possessing select agents if they are nationals of countries as to which the Secretary of State (pursuant to provisions of the Export Administration Act of 1979, the Foreign Assistance Act of 1981, or the Arms Export Control Act) has made an unrevoked determination that such countries have repeatedly provided support for acts of international terrorism. **(LINK WITH FOCUS AREA D)**

*Strategies: What overarching approach(es) will be used to undertake this activity?*

- 1. Continue upgrade of PHL security to meet current CDC standards for possession, use and transfer of select agents (LINK TO FOCUS AREA D)
- 2. Ensure PHL staff are in compliance with the Patriot Act of 2001 regarding select agents
- 3. Continue with risk assessments of BT protocols to ensure PHL staff are in a safe working environment

*Tasks: What key tasks will be conducted in carrying out each identified strategy?*

- 1a Identify updates in CDC recommended standards for laboratory security for select agents
- 1b Purchase equipment/supplies required to meet CDC recommended standards
- 1c Identify security classes and send RO and ARO for training
- 2a Review elements of Patriot Act to ensure compliance
- 2b PHL staff involved in the handling of select agents will undergo a security risk assessment





- 3a Complete risk assessment evaluations for all bioterrorism protocols
- 3b Purchase equipment/supplies to ensure safe working environment
- 3c Identify testing and safety needs of surge capacity laboratories and include required upgrades in contracts/ cooperative agreements

*Timeline: What are the critical milestones and completion dates for each task?*

- 1a 9/03
- 1b 1/04
- 1c Ongoing
- 2a 12/03
- 2b 10/03
- 3a 12/03
- 3b Ongoing
- 3c 12/03

*Responsible Parties: Identify the person(s) and/or entity assigned to complete each task.*

- 1a Div ERP
- 1b Operations Manager
- 1c Training Manager
- 2a QA/QC Coordinator
- 2b Div ERP
- 3a Div ERP
- 3b Safety Officer
- 3c BT Coordinator

*Evaluation Metric: How will the agency determine progress toward successful completion of the overall recipient activity?*

- 1a Updated standards
- 1b Purchase orders
- 1c Training documentation
- 2a Change documentation
- 2b Risk assessment documentation
- 3a Risk assessment documentation
- 3b Purchase orders
- 3c Consolidated contracts & MOUs

7. Enhance electronic communications and LRN electronic laboratory reporting, at the bench level, to enable integration with CDC's LRN capacity monitoring efforts, online results reporting, sentinel surveillance, proficiency testing, multi-center validation studies, and support for future LRN site enhancements. Laboratories should participate in reporting results of LRN proficiency testing electronically, as they would in an actual event. Laboratories should have appropriate computer equipment, firewall and high-speed Internet connectivity to access the LRN's protocols, reagents, and lab user applications. **(LINK WITH FOCUS AREA D, E AND CROSS CUTTING ACTIVITY LABORATORY DATA STANDARD, Attachment X)**



*Strategies: What overarching approach(es) will be used to undertake this activity?*

1. Plan for PHL LIMS conformity with APhL Requirements document
2. Continue development of PHL LIMS (Link with Focus Area E)
3. Include secure web interface with PHL LIMS
4. Participate with CDC to evaluate and determine the core information technology capacity required to optimally respond to bioterrorism events (APHL)
5. Provide "need to know" accessibility to LRN labs on testing capabilities and capacities (APHL)
6. Maintain videoconferencing equipment (Link to focus area G)
7. Purchase communication equipment (computers, etc.)
8. Assess the hardware, software, and high-speed Internet connectivity capabilities of the LRN sites and develop a plan to capitalize on these resources to develop laboratory-based electronic exchange of data (Link to Focus Area E)
9. Participate with APhL/CDC to evaluate and determine the core information technology capacity required of PHLs to optimally respond to bioterrorism events (Link to Focus Area E)

*Tasks: What key tasks will be conducted in carrying out each identified strategy?*

- 1a Review APhL LIMS requirements
- 1b Incorporate LIMS requirements in PHL planning for LIMS development
- 2 Plan meetings with APhL, CDC and PHL IT staff to develop seamless LIMS
- 3 Coordinate development of secure web interface with PHL IT staff APhL and CDC
- 4a Collaborate with APhL and CDC to evaluate and determine the core information technology capacity required to optimally respond to bioterrorism events
- 4b Implement collaborative findings
- 5a Establish "need to know" accessibility requirements in collaboration with CDC
- 5b Implement CDC requirements
- 6 Identify videoconferencing needs and maintain/purchase necessary equipment
- 7a Evaluate the need for communication equipment at PHL and surge capacity laboratories (Link to Focus Area E)
- 7b Purchase required equipment to maintain communication with CDC and collaborative partners
- 8a In collaboration with CDC, APhL and LRN sites, assess LRN site capabilities
- 8b Develop plan to capitalize on existing resources
- 8c Implement plan for efficient use of existing resources
- 9a Participate with APhL and CDC to evaluate and determine core information technology capacity of PHL
- 9b Implement plan to ensure the PHL meets and continues to meet core information technology capacity

*Timeline: What are the critical milestones and completion dates for each task?*



- 1a 9/03
- 1b 12/03
- 2 Ongoing
- 3 Ongoing
- 4a Ongoing
- 4b 9/03
- 5a 10/03
- 5b Ongoing
- 6 9/03
- 7a-b Ongoing
- 8a Ongoing
- 8b-c 9/03
- 9a-b 12/03

*Responsible Parties: Identify the person(s) and/or entity assigned to complete each task.*

- 1-5b LIMS Coordinator
- 6 PHL Help Desk
- 7-9b LIMS Coordinator

*Evaluation Metric: How will the agency determine progress toward successful completion of the overall recipient activity?*

- 1a Requirements document
- 1b Planning document
- 2 Meeting agenda
- 3 LIMS Security Plan
- 4a Requirements document
- 4b Charter - LIMS development
- 5a Requirements
- 5b Implementation plan
- 6 Purchase orders
- 7a Evaluation documentation
- 7b Purchase order
- 8a Assessment
- 8b Completed Plan
- 8c Document implementation
- 9a Evaluation of IT capacity
- 9b Document implementation

- 8. (Smallpox) Identify the laboratories that have the capacity for LRN-validated testing and reporting of *Variola major*, *Vaccinia* and *Varicella* through human and environmental samples. Each state should have at least one laboratory that can meet CDC biosafety and security requirements for variola-specific testing.



*Strategies: What overarching approach(es) will be used to undertake this activity?*

1. Ensure appropriate staff is vaccinated and that plans are included for vaccination of additional staff in the event of a smallpox release.
2. Pre-event smallpox planning and coordination (Link to Focus Area B)
3. Review established smallpox emergency procedures (including the testing of human and environmental specimens) for Low, Medium and High Risk specimens (Link to Focus Area B)
4. Continue development of MOU with [REDACTED] for Variola major, Vaccinia and Varicella
5. Update protocols for specimen handling
6. Ensure adequate test collection supplies (Link to Focus Area B)
7. Review smallpox "Rule-out or Refer" capability
8. Develop coordinated plans with sentinel laboratories for specimen collection and processing for low, moderate and high risk patients. Provide training on use of clinical and laboratory febrile rash algorithm for sentinel laboratories (APHL)
9. Update EM training of PHL staff (Link to focus area G)
10. Continue with plans for increased BSL-3+ capacity at the PHL

*Tasks: What key tasks will be conducted in carrying out each identified strategy?*

- 1a Perform needs assessment for appropriate vaccinations
- 1b Obtain necessary vaccinations for staff
- 2a Review existing pre-event smallpox response plan and update as necessary
- 2b Coordinate review and update of smallpox plan with Epidemiology
- 3a Review CDC website for updates to smallpox emergency procedures
- 3b Identify team to review smallpox emergency procedures
- 3c Coordinate smallpox review with Epidemiology and CDC
- 4a Continue process of establishing MOU with [REDACTED] for smallpox-related testing
- 4b In an MOU [REDACTED], include cross training for continued collaboration on laboratory procedures
- 5a Review smallpox protocols for specimen handling
- 5b Update protocols as necessary
- 6a In cooperation with CDC and Epidemiology, identify optimal number of smallpox test collection kits necessary for distribution to regional sites
- 6b Purchase enough test components to ensure adequate supply of kits
- 7a Review "Rule-out or Refer" protocols with CDC, Epidemiology and LHJs
- 7b Ensure Level A training protocols reflect current accepted procedures
- 7c Update Level A laboratories on any changes to smallpox "Rule-out or Refer" capability through *Elaborations* newsletter and DOH website
- 8a Review and update coordinated plans for sentinel laboratories as necessary
- 8b Update training plan as necessary
- 8c Provide training to LRN Level A/B laboratories on febrile rash algorithm
- 9 In cooperation [REDACTED]



	continue/update EM cross-training of staff to ensure adequate coverage
10a	Review plans for increased BSL-3+ capacity and update as necessary
10b	Ensure MOUs for BSL-3 surge capacity are adequate and up to date.
10c	Update protocols for implementation of surge capacity for smallpox

*Timeline: What are the critical milestones and completion dates for each task?*

1a-b	Ongoing
2a-b	2/04
3a	Ongoing
3b	12/03
3c	3/04
4a	10/03
4b	Ongoing
5a-b	Ongoing
6a-b	1/04
7a--c	2/04
8a-b	Ongoing
8c	6/04
9	Ongoing
10a-b	9/03
10c	1/04

*Responsible Parties: Identify the person(s) and/or entity assigned to complete each task.*

1a-b	Safety Officer
2a-b	BT Coordinator
3a-b	Micro OD
3c	BT Coordinator
4a	PHL Dir
4b-7a	Micro OD
7b-c	LPA
8a	BT Coordinator
8b-c	LPA
9	Micro OD
10a	Operations Manager
10b-c	PHL Dir

*Evaluation Metric: How will the agency determine progress toward successful completion of the overall recipient activity?*

1a	Needs assessment
1b	Vaccination documentation
2a	Updated plan
2b	Planning documentation
3a	Updated plans
3b	Meeting agenda
3c	Updated plans



- 4a Finalized MOU
- 4b Training schedule
- 5a-b Updated protocol
- 6a Smallpox test plan
- 6b Purchase orders
- 7a Updated protocols
- 7b Training plans
- 7c Training schedule
- 8a Updated plans
- 8b-c Training plans
- 9 Training schedule
- 10a Plans
- 10b Finalized MOUs
- 10c Updated protocols